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10/563,637	06/12/2006	Christopher Milton Mathew Franco	19460	4137

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EXAMINER	
GUPTA, ANISH	

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1654	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/563,637	FRANCO ET AL.	
	Examiner	Art Unit	
	ANISH GUPTA	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-37 and 39-48* is/are pending in the application.

4a) Of the above claim(s) *1-35, 37, 40-45* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,39 and 46-48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6/28/2010 has been entered.

2. Applicants' amendment to the claims and the specification is acknowledged. Applicants amended claims 36 and39 and added claims 47-48. Claims 1-48 are pending in this application.

3. Applicant's election of Group IX, claims 36, 39 in the reply filed on 9-8-08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Applicants also elected SEQ ID NO 7 as the species for examination. Prior art was found on this species in the reference entitled Coombs (Thesis). This reference teaches all of the species claimed. Additional prior art has been applied to another EN27. See MPEP 803.02.

Claims 36, 39 and 46-48 are examined in this Application. Claims 1-35, 37 and 40-41 are withdrawn form consideration.

Information Disclosure Statement

4. In the IDS filed March 20, 2009, Applicants cited the reference of "Coom, J.T." entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date Applicants provided was 2004. However, it is unclear if the date of this

reference is actually 2004. First, the date of the publication never Appears on the reference it self. The only date present is the "Approved by the FHDC" date which is 2001. More importantly, Applicants have indicated in Journal articles that the date is not 2004, but is actually 2002. For example in Journal Plasmid, Applicant Journal Article entitled "Complete sequencing and analysis of pEN2701, a novel 13-kb plasmid from an endophytic Stretomyces sp.," Applicants cited the PHD thesis of Coombs. This too was entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." The date of this publication however was indicated as 2002. Furthermore, a search on the Flinder University Library system yielded a result for a PHD thesis entitled "The Isolation and Characterisation of Endophytic Actinomycetes from Wheat (Triticum aestivum)." Again this is the same title as Applicants thesis. This was indicated as being published on 2001. Note that the Thesis submitted by Applicants indicates Flinders University. Applicants are requested to clarify the date of the publication submitted. Absent evidence to the contrary the thesis was publically available on 2001 (using the Flinder Library date) and this date has been utilized for this reference for prior art purposes.

5. All rejections made in the previous office action and not cited herein are hereby withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 39 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The MPEP states that the purpose of the written description requirement is to ensure that the inventor had possession, as of the filing date of the application, of the specific subject matter later claimed by him. The courts have stated:

> "To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966." Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP lists factors that can be used to determine if sufficient evidence of possession has been furnished in the disclosure of the Application. These include "level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient." MPEP 2163.

Further, for a broad generic claim, the specification must provide adequate written description to identify the genus of the claim. In Regents of the University of California v. Eli Lilly & Co., the court stated:

> "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials. Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606; In re Smythe, 480 F.2d 1376, 1383, 178 USPQ 279, 284-85 (CCPA 1973) ("In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus. . . ."). Regents of the University of California v. Eli Lilly & Co., 43 USPQ2d 1398.

The MPEP further states that if a biomolecule is described only by a functional characteristic, without any disclosed correlation between function and structure of the sequence, it is "not sufficient characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." MPEP 2163. The MPEP does state that for generic claim the genus can be adequately described if the disclosure presents a sufficient number of representative species that encompass the genus. MPEP 2163. If the genus has a substantial variance, the disclosure must describe a sufficient variety of species to reflect the variation within that genus. See MPEP 2163. Although the MPEP does not define what constitute a sufficient number of representative, the Courts have indicated what do not constitute a representative number species to adequately describe a broad generic. In Gostelli, the Court determined that the disclosure of two chemical compounds within a subgenus did not describe that subgenus. In re Gostelli, 872 F.2d at 1012, 10 USPQ2d at 1618.

For written description, the analysis (a) considers actual reduction to practice, (b) disclosure of drawing or structural chemical formulas, (c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed.

In the instant case, claims 38 and 39 recite metabolites derived from the nucleic acid sequence and antibodies directed to the actiomycete or the metabolites. This recitation does not provide written description for the claimed invention.

(a) actual reduction to practice/(b) disclosure of drawing or structural chemical formulas:

The specification fails to provide any species that correspond to a metabolite or antibody. The specification states that a "metabolite" should be understood as a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. The specification fails to provide a single example of a proteinaceous or non-proteinaceous molecule that would be a metabolite for SEQ ID NO 7 or an antibody against SEQ ID NO 7.

(c) sufficient relevant identifying characteristics in the way of complete/partial structure or physical and/or chemical properties, functional characteristics when coupled with known or disclosed:

The metabolites and antibodies are also defined solely by functional limitations. The specification defines “metabolite" is a reference to any proteinaceous or non-proteinaceous molecule produced by the subject endophytic actinomycetes or produced by the plant in response to the actinomycete colonisation or actinomycete metabolite actions which directly or indirectly modulate the metabolism or other functional activity of the host plant. However, the specification fails to provide any specific structures for the protein or non-protein molecules that could be construed as metabolites. Similarly, for antibodies, the specification fails for provide any relevant identifying characteristics in the way of complete/partial structure.

(d) Representative number of examples

However, the specification fails to provide a single example that would fall within the broad definition of the claimed invention for metabolites and antibodies. The definition for metabolites is all encompassing since they can include any compound that remotely has activity directly or

indirectly to modulate the metabolism or other functional activity of the host plant. The specification does not provide a single compound, either a protein, peptide or small molecule, that would be considered a metabolite for SEQ ID NO 7. The specification simply fails to provide a representative number of species for the broad genus claimed for variants of SEQ ID NO 7, metabolites and antibodies. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 1521, 222 USPQ 369, 372-73 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Response to Arguments

Applicants ague that "those skill in the art would appreciate that such antibodies can be radily prepared, and thus there is no need for the specification to explicitly detail the generation of such antibodies."

Applicant arguments have been fully considered but have not been found persuasive.

First, the rejection made for claim 39 is under Written Description and not under Enablement "how to make" prong. Thus whether one skill in the art can make the compound is not at issue. The issue is whether Applicants provided ample written description to establish possession of an antibody raised against actinomycete. As stated in the previous office action, the description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Applicants have not provided any evidence that they were in possession antibodies. Applicants have stated that one skilled in the art would readily be able to make the antibodies. However, this does not fulfill the written description criteria. For a genus claim, the written description requirement for a claimed genus may be satisfied through

sufficient description of a representative number of species by actual reduction to practice (see i)(A), above), reduction to drawings (see i)(B), above), or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the claimed genus (see i)(C), above). See MPEP 2163. Here, the antibodies encompassed by the claims are described in relevant, identifying characteristics, i.e., structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure nor qualifies as a representative number of species by actual reduction to practice.

Thus, the rejection is maintained.

New Grounds For Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 36, 39 and 46-48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 36, the claim states that the anctinomycete characterized either by a nucleic sequence corresponding to the nucleotide sequence substantially as set forth SEQ ID No. . . It is unclear what substantial correspondence to this sequence would qualify as. That is to say it is

unclear what percent of homology is necessary to render a sequence "substantially" corresponding to the sequence.

New Matter

8. Claims 36, 48 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the amendment filed, 6/28/2010, Applicants amended the claims, for all SEQ ID numbers, to recite that a nucleic sequence capable of hybridizing to the sequence under "high stringency conditions at 42oC." The claims previously recited "low stringent" conditions. This amendment introduces new matter for the following reasons.

The originally filed disclosure, when discussing stringency in with respect to the claimed SEQ ID NO, stated "(g) An actinomycete characterised either by a nucleotide sequence corresponding to the nucleotide sequence substantially as set forth in <400>7 or a nucleotide sequence capable of hybridising to <400>7 under low stringency conditions at 42.degree. C. or a variant, mutant or homologue of said actinomycete." (see page 6). The recitation of "low stringency conditions at 42.degree. C." was repeated for every sequence and repeated on pages 13, 19, 44, 66, 77 for sequence ID NO 7. The recitation of "low stringency conditions at 42.degree. C." does not provide *ipsis verbis* support of high stringency as not claimed. Indeed, the originally filed disclosure never mentions "high stringency" with respect to SEQ ID NO 7 nor any sequence recited or claimed.

The MPEP states "[w]hile there is no in *haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure." See MPEP 2163(1)(B). Thus, the amended claims can be supported via implicit or inherent support. However, the originally filed disclosure does not provide any implicit or inherent support for the claimed invention. On page 51-52, the disclosure defines high stringency "includes and encompasses from at least about 31% v/v to at least about 50% v/v formamide and from at least about 0.01M to at least about 0.15M salt for hybridization, and at least about 0.01M to at least about 0.15M salt for washing conditions." While the specification mentions high stringency, it never states that these conditions are utilized obtain "nucleotide sequence capable of hybridizing to SEQ ID NO 7." Whenever SEQ ID NO 7 is mentioned only low stringency conditions are outlined. As outlined on page 51-52 the low conditions are different than the high stringency conditions. The low stringency condition would lead to different nucleic acid sequence that hybridize to SEQ ID NO 7. One could not and would not be able to conclude that the sequences obtained under low stringency condition are the same as those obtained form high stringency conditions. Based on the emphasis of low stringency condition taught through out the specification, one could not conclude that the specification also intended to hybrize under high stringency conditions for SEQ ID NO 7. The specification does not provide a single example where SEQ ID NO 7 was hybridized under high stringency conditions. Thus, the instant disclosure lacks implicit or inherent support.

Since the originally filed disclosure does not provide support for the claimed limitation, the claims contain new matter.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 36 and 48 are rejected under 35 U.S.C. 102(a) as being anticipated by Coombs et al. (Plasmid, Jan. 2003).

The claims are drawn to isolated endophytic actinomycete.

The reference teaches pEN2701 which reads on the sequence claim 36, SEQ ID NO 12 (see page 90). This anticipates the claimed invention.

10. Claims 36 and 46-48 are rejected under 35 U.S.C. 102(a) as being anticipated by Coombs (Thesis, 2001).

The claims are drawn to isolated endophytic actinomycete.

The reference teaches all of the endophytic actinomycete claimed in the instant application. Specifically, the reference teaches the sequence corresponding to pEN27 which reads on the sequence claim 36, SEQ ID NO 12 (see page 195). The reference also states that endophytes were isolated form root tissue and wheat seeds (see page 75). The reference states that the DNA was extracted and sequenced (see page 78-79). The reference specifically states that isolate named EN007 was isolated from YCED/B (see page 87). The reference teaches that EN7 has a 93% match to GenBank ane EMBL databases (See page 90-91). It should be noted that this is the same result recited in the instant specification in Table 3 (page 118 of the instant specification). Also note that the table 2.5 taught in the reference on page 95 is identical to the table 2 disclosed on page 117 of the instant application. Thus, since the reference discloses endophytic actinomycetes from

the same source having the same characteristics, the endophytic actinomycete taught in the reference anticipates the claimed invention.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anish Gupta whose telephone number is (571)272-0965. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can normally be reached on (571) 272-0562. The fax phone number of this group is (571)-273-8300.

/Anish Gupta/
Primary Examiner, Art Unit 1654